AVflo™ Vascular Access Graft

Instructions for use

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Nicast

ENGLISH

Sterile (EO) – For Single Use Only

⚠	***Caution***
	Federal (USA) law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

1. GENERAL

Read all instructions carefully. Failure to properly follow the instructions, warnings and precautions may lead to serious consequences or injury to the patient.

2. DESCRIPTION

The AVflo™ Vascular Access Graft is made of medical grade polycarbonate urethane nanofibers supplied in both straight and coiled pre-sterilized configurations. The coiled configuration is manufactured with an additional polyethylene terephthalate (PET) reinforcement segment for improvement of kink resistance and may be found in two versions: Centered-coil or off-centered coil configurations. Straight and centered-coil U-bend graft configurations are used for implantation in the lower and upper arm while off-centered coil configuration is usually used for J-bend implantation in the upper arm.

The graft features a self-bonded, four-layer design:

The nanofiber microporous blood-contacting **inner** layer is designed to minimize platelet adhesion. The microporous **middle** layer contains a 40µm thick **barrier** layer which prevents the diffusion of large molecules and provides strength and elasticity to the graft's structure. In the coiled AVflo™ vascular access graft configuration

the barrier layer also secures the anti-kinking coiled segment in place. The nanofiber's **outer** layer is designed to enhance graft anchoring via tissue ingrowth. The design supports the self sealing properties of AVflo™.

3. PROPOSED INDICATIONS FOR USE

The AVflo™ vascular access graft's proposed indication for use is as a subcutaneous, arteriovenous conduit for blood access.

4. CONTRAINDICATIONS

Do not use on patients with a known sensitivity / allergy to polycarbonate urethanes and PET.

5. POTENTIAL COMPLICATIONS

Potential complications that may occur with any surgical procedure involving a vascular prosthesis include (but not limited to): aneurysm; anastomotic disruption or tearing of the suture line and/or host vessel; embolic events; infection; bleeding; stenosis; thrombosis; kinking or compression; swelling of the implanted limb; formation of hematomas, seromas or pseudoaneurysms; steal syndrome leading to peripheral ischemia. Hypotensive episodes (including Hemodialysis-induced hypotension (HIH))

6. WARNINGS ⚠

AVOID CONTACT OF THE AVflo™ WITH ORGANIC SOLVENTS.

AVOID EXCESSIVE AXIAL ELONGATION OR STRETCHING OF THE AVflo™ (>15%) DURING HANDLING AT IMPLANTATION.

Cut the graft long enough to prevent excessive stress on the anastomoses sites and/or to allow for a full range of body movements. Excessive elongation or stretching of the graft may result in damage to the graft's microporous layers, or anastomotic disruption that could lead among other things to hematoma, bleeding, pseudoaneurysm, or ischemia.

DO NOT USE AN UNSTERILIZED GRAFT.

Do NOT use the product if its package has been damaged or opened, as sterility may be compromised.

Do NOT re-sterilize the graft.

DO NOT REUSE GRAFT.

The AVflo™ is in intimate contact with the patient's blood and surrounding tissue; reuse of an explanted graft on another patient may result in dissemination of blood and skin transmitted pathogens, and in induction of immune response. Therefore transferring of graft between different patients is forbidden.

7. PRECAUTIONS

7.1. Preclotting this graft is not recommended.

7.2. Hydrate the graft in a sterile physiologic saline solution prior to implantation. The inner and outer luminal walls of the graft are microporous and the voids in these surfaces contain air that must be displaced (see Operative Techniques #8.3 for more information).

7.3. Use of a tunneler sheath is mandatory to minimize subcutaneous trauma and to minimize the force required to position the graft during implant. Pulling the graft without the use of a tunneler sheath might result in damage to the graft.

7.4. If clamping of the AVflo™ is necessary, use only atraumatic, or appropriate vascular smooth-jawed, or shod clamps to avoid damage to the graft wall during implantation. In any event, do not press the coiled region of the AVflo™ coiled configurations by using an instrument or manually.

7.5. Guideline 17 of the Clinical Practice Guidelines from the Final Report of the Vascular Access Work Group of the National Kidney Foundation (US) - Dialysis Outcomes Quality Initiative, recommends the following for infected arteriovenous grafts:

"When infected, a dialysis graft should be treated surgically. An untreated access infection may lead to bacteremia, sepsis, hemorrhage, and death. Surgical exploration and removal of any infected graft or graft segment is necessary for resolution of the infection because the graft material acts as a foreign body unless eliminated."

Keeping the graft in a contaminated environment for more than one week may soften the graft's structure and it is not recommended.

7.6. When using a balloon angioplasty or an embolectomy catheter within the lumen of the AVflo™, match the inflated balloon size to the inner diameter size of the graft. Do not puncture the coiled region of the AVflo™ graft. Over-inflation of the balloon or use of an inappropriately sized balloon catheter may damage the graft. Care must be exercised to avoid causing excessive axial elongation of the graft during retraction.

⚠	***Caution***
	Some tunneler sheaths are reusable. If reused, make sure that they are clean and sterilized prior to re-using.

8. OPERATIVE TECHNIQUES

8.1. *Opening the Package*

Open the sterile package using and maintaining sterile technique only. Carefully remove the graft using sterile atraumatic instruments or gloves.

8.2. *Create ample pockets and windows for the AVflo™*

Create ample pockets and windows in the fascia to avoid constriction of the AVflo™'s apex (in U-Bend implantation), in order to allow for slight elongation of the AVflo™ following de-clamping and blood pressure buildup.

8.3. *Hydrating the Graft*

Prior to implantation, hydrate or soak the graft in a sterile solution of normal physiologic saline. While soaking, gently compress the submerged graft to displace the air from the voids in the porous structure. When the bubbling stops, air has been displaced and you may proceed with the graft implantation.

⚠	***Warning***
	For coiled configuration: Compression of the coiled segment may damage the graft.

⚠	***Caution***
	For all configurations: Trim to allow proper sizing of the graft. Avoid bending when positioning and trimming the graft, especially near or at the anastomotic ends.

⚠	***Caution***
	For coiled configuration: Trim the graft at least 10mm from the coiled's edges to avoid exposure of the coiled segment which could lead to laceration of the adjacent tissue and anastomotic bleeding. Avoid bending when positioning and trimming the graft, especially near or at the anastomotic ends.

8.4. *Tunneling*

Because the graft may be damaged if pulled excessively, use of a tunneler sheath is mandatory. The tunneler sheath is designed to permit graft placement by gently pushing the graft through the tunneler hollow shaft rather than pulling. Please refer to the Tunneler sheath's Instructions for Use.

Irrigate the inside of the tunneler hollow shaft liberally as well as all surfaces of the graft with normal sterile physiologic saline to facilitate easier slipping of the graft through the tunneler sheath.

⚠	***Caution***
	Care should be taken to push rather than pull the graft through a tunneler sheath. Use a tunneler sheath having an internal diameter of at least 9 mm.

8.4.1. Tunneling and implantation of STRAIGHT configuration

8.4.1.1. Make incisions for distal and proximal entries of the implant sites.

8.4.1.2. Insert the tunneler sheath's bullet tip onto the end of the tunneler sheath's hollow shaft.

8.4.1.3. Insert the fully assembled tunneler sheath into one of the incisions to create a subcutaneous tunnel between the distal and proximal incisions.

8.4.1.4. Make sure the tunneler sheath is placed at a suitable subcutaneous depth that will allow proper hemodialysis needle insertion and palpation of the AVflo^{TM} graft blood flow.

8.4.1.5. With the bullet tip of the tunneler sheath exposed, the bullet tip is removed leaving the tunneler shaft in place subcutaneously.

8.4.1.6. Insert the graft into the subcutaneously placed tunneler sheath's hollow shaft and gently push the graft through the hollow shaft, using a gentle rotating motion if necessary, while irrigating liberally with sterile saline.

⚠	***Caution***
	Do NOT pull the graft through the tunneler sheath. Do NOT twist the graft. Do NOT attempt to reposition the graft after the sheath removal.

8.4.1.7. When positioning of the graft is complete, carefully remove the hollow sheath leaving the graft in place subcutaneously (see Figures 1& 2).

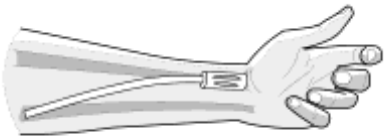


Figure 1. Placement of Tunneler Sheath for straight configuration implantation

Figure 2. Completed straight graft positioning

8.4.2. Tunneling and implantation of CENTERED-COIL configuration

8.4.2.1. Make incisions for distal window and proximal entries of the implant sites.

8.4.2.2. Insert the tunneler sheath's bullet tip onto the end of the tunneler sheath's hollow shaft.

8.4.2.3. Insert the fully assembled tunneler sheath into the window in the direction of one of the incisions to create a subcutaneous tunnel between the distal window and proximal incision.

8.4.2.4. Make sure the tunneler sheath is placed at a suitable subcutaneous depth that will allow proper hemodialysis needle cannulation and proper palpation of the AVflo™ graft.

8.4.2.5. With the bullet tip of the tunneler sheath exposed, the bullet tip is removed leaving the tunneler shaft in place subcutaneously.

8.4.2.6. Insert the first section of the graft into the subcutaneously placed tunneler sheath's hollow shaft and gently push the graft through the hollow shaft, using a gentle rotating motion if necessary, while irrigating liberally with sterile saline.

⚠	***Caution***
	Do NOT pull the graft through the tunneler sheath. Do NOT twist the graft. Do NOT attempt to reposition the graft after sheath removal.

8.4.2.7. When positioning of the graft is completed, carefully remove the hollow sheath leaving half of the graft in place subcutaneously.

8.4.2.8. Repeat steps 8.4.2.2 to 8.4.2.3 while allowing for minimal distance of 1" (2-3cm) between the 2 branches of the implanted AVflo™ graft during tunneling.

8.4.2.9. Make sure the centered-coil graft U-bend apex is located exactly in the middle of the distal window to prevent graft kinking at the coiled non-coiled borders of the graft (see Figure 3 & 4)

8.4.2.10. Repeat steps 8.4.2.4 to 8.4.2.7.

8.5. *Implantation Tips and Technique*

The AVflo™ may expand longitudinally by up to 5 mm once exposed to normal blood flow after de-clamping.

- Use the longitudinal orientation black markings featured on the graft to facilitate proper graft positioning.
- In U-bend implantation of centered-coil configuration, make sure there is a sufficient space for graft's apex expansion and elongation by creating ample subcutaneous pocket in order to prevent apex shape deformation.
- When performing the anastomoses in all the AVflo™ configurations, trim the graft's edges to a length approximately 0.5cm shorter than the length measured. Pull each end to keep it slightly tensed when performing anastomosis to the vessel.
- The edges of the graft should be beveled and anastomosed in such way to accommodate a smooth positioning of the graft and to prevent graft's edges kinking.

⚠	***Caution***
	Do NOT pull the graft through the tunneler sheath. Do NOT twist the graft.

	Do NOT attempt to reposition the graft after sheath removal. Ensure a maximal radius at the distal part.

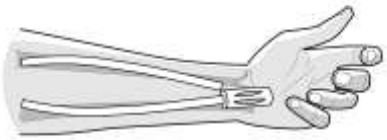


Figure 3. Placement of tunneler sheath for coiled configuration implantation

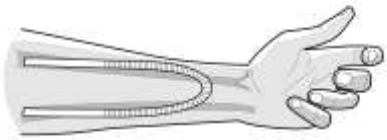


Figure 4. Completed coiled graft positioning

8.6. *Anastomotic Preparation*

Once the graft is properly positioned, an anastomosis should be made between the vessels and the graft. The anastomosis may be performed using a one- or two-suture technique. The other end of the graft should be trimmed and anastomosed in the same manner.

8.7. *Graft Suturing*

Best results are achieved using a tapered, non-cutting needle with Prolene 5.0/6.0 sutures. There is no need for using ePTFE suture. Use the positioning black mark to prevent twisting of the AVflo™ during the anastomosis creation and as a landmark for suturing. Care must be taken to follow the curve of the needle and pull the suture at a 90° angle, assuring that the needle penetrates all layers of the graft to minimize suture hole elongation and bleeding. Use systemic or local heparinization unless contraindicated.

8.8. *Final Suturing*

Surgeon should consider the necessity of installing a draining catheter at the site of implantation to avoid fluid collecting.

⚠	***Caution***
	Suturing should be positioned about 1mm from the edge of the graft at the anastomoses sites. Greater distance may induce tension force on the vein wall with subsequent bleeding. Elongation of suture holes or gaps between the graft and host vessel could lead to anastomotic bleeding Thus, avoid: (1) Excessive tension that may cause suture holes to elongate or tear. (2) Undue tension on the suture line. (3) Gaps between the graft and host vessel and (4) inappropriate suture placement and bites.

Please refer to "The 7 Important Principles for Implanting Nicast's AVflo™ Graft" brochure for additional information.

9. CANNULATION

	Note
	Puncturing of the AVflo™ may be considered for vascular access within 24-48 hours after implant, provided that no contraindications are present (see # 9.4 below).

Insert the blood access (dialysis) needle at a 45° angle with the bevel facing up until the graft is penetrated. If the blood access needle is inserted such that the angle between the needle axis and the graft is too small, tears in the wall of the graft may occur. If the needle is inserted at a 90° angle, it increases the possibility of puncturing the far wall of the graft, which may lead to hematoma formation.

⚠	***Caution***
	For coiled configuration: Do NOT insert the blood access needle through the coiled segment of the graft.

For best results follow the established cannulation practices listed below:

9.1. Rotate cannulation sites: repeated cannulation in the same puncturing site ("buttonhole technique") may lead to damage of the graft wall and/or formation of hematomas or pseudoaneurysms and is not recommended.

9.2. Do not cannulate within the dialysis needle's length of the proximal or distal anastomoses.

9.3. Strict adherence to aseptic technique is required to minimize infection.

9.4. As with all dialysis, do not cannulate if there are any signs of infection, bleeding, swelling, edema, hematoma, or in the absence of a strong "thrill".

After needle withdrawal, **use gentle, non-occlusive manual pressure** to compress the cannulation site to aid in hemostasis; the AVflo^{TM} graft is expected to seal quicker and with less applied pressure compared to most commercially available ePTFE grafts.

⚠	***Caution***
	Prolonged compression or use of stasis clamps or pressure cuffs may lead to clot formation, restricting flow through the graft.

Please refer to "The 5 Important Principles for Dialysis" brochure for additional information.

10. THROMBECTOMY

The AVflo^{TM} may be declotted with an embolectomy balloon catheter using standard arterial embolectomy / thrombectomy procedures and precautions. The balloon diameter should not exceed 6mm. (Note: the F number of 6mm thrombectomy balloon catheters differs among various suppliers).

Care must be taken not to over-inflate the balloon catheter. The wall of the AVflo^{TM} is more flexible than the wall of an ePTFE graft, and over inflation may dilate or damage the graft.

Do not use excessive pulling force when passing through the arterial and / or venous anastomoses regions or the luminal section of the graft when placing or removing the embolectomy balloon catheter.

⚠	***Caution***
	If performing the thrombectomy on a vascular graft containing a coiled section (centered coil or off-centered coil AVflo^{TM} configurations), care must be taken not to access the graft lumen through the coiled section. This may lead to irreparable damage to the graft.

11. SURGICAL REVISION

If it becomes necessary to repair the graft with a surgical interposition bypass graft, the use of the AVflo™ should be considered.

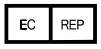
12. STORAGE

To provide maximum protection, store the grafts in their original, unopened packages at room temperature (-10°C to 50°C). Avoid excessive heat or cold.

The grafts must be used before the expiration date printed on the package label.

⚠	***Caution***
	The AVflo™ should be removed from its package only in a sterile environment.

13. LABEL GRAPHICAL SYMBOLS

SYMBOL	
	Use by
	Serial number
	Single use only
	Do not resterilize
	Catalog number
	Consult instructions for use
	Do not use if package is damaged
	Method of sterilization using ethylene oxide
	Keep dry
	Keep away from sunlight
	Temperature limitation
	Authorized representative in the european community
	Manufacturer

14. DISCLAIMER OF WARRANTIES

Many factors are outside Nicast Ltd.'s supervision and control after sale of this device. Nicast has no control over the conditions under which the device is used, the diagnosis of the patient or the methods or procedures used for implantation. Therefore, Nicast makes no warranty or guaranty of this device, express or implied.

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Some jurisdictions do not allow the exclusion of or limitation on an implied warranty. Similarly, some jurisdictions do not allow the exclusion of limitation of incidental or consequential damages. Therefore, some of the above exclusions may not apply. This warranty gives specific legal rights. The patient may also have other rights, which vary from jurisdiction to jurisdiction.

CE **0482**

Authorized European Representative:
MedNet GmbH
Borkstr. 10
48163 Muenster
Germany
Tel +49 251 32266-0
Fax +49 251 32266-22

Nicast Ltd.,
2 Yodfat St,
Lod 71291
Israel
www.nicast.com
Tel. +972 (8) 9153001
Fax +972 (8) 9153002